

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO: <i>Ida DeAnne Evans v. Ethicon, Inc., et al.</i> <i>2:12-cv-01225</i>	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION FOR
SUMMARY JUDGMENT**

Plaintiff Ida Deanne Evans states the following in opposition to Defendant Ethicon, Inc.'s Motion for Summary Judgment:

I. INTRODUCTION

In its Motion, Defendant repeatedly misstates Utah law and ignores important facts in an effort to persuade this court to grant summary judgment. As set forth below, Plaintiff's claims are not barred by the statute of limitations and Defendant has failed to meet its burden to establish that no genuine issues of material fact exist as to Plaintiff's claims and therefore summary judgment should be denied.

II. COUNTER STATEMENT OF FACTS

1. Ms. Evans did not appreciate that the mesh could be causing her problems until she read a 2010 Reader's Digest article (Ex. A, p. 95-96).
2. Ms. Evan's implant surgeon, Dr. Stout, could not even conclude the mesh was causing her problems when Ms. Evans saw her after reading the 2010 article (Ex. A, p. 101-102).

3. At the time she spoke with Dr. Brouse in 2009, Ms. Evans was unaware the mesh could be a source of her petroleum toxicity (Ex. A, p. 136-137).
4. One of Ms. Evan's primary complaints is chemical toxicity caused by the Prolene mesh and resulting auto-immune reaction (Ex. B, paragraph 23).
5. Dr. Stout did not testify that she didn't read materials provided by Defendant, only that she could not recall reading them (Ex. C, p. 45).
6. Dr. Stout did not testify that she wouldn't have altered her decision had there been an alternative warning (Ex. C, p. 45).
7. A consulting firm retained by Defendant concluded that Defendant's mesh products may have a manufacturing defect (Ex. D, p. 24-33).

III. STANDARD OF LAW

To prevail on its Motion, Ethicon must show that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The court will not "weigh the evidence and determine the truth of the matter" on a summary judgment motion. *Anderson v. Liberty Lobby, Inc.* 477 U.S. 242, 249 (1986). Rather, the court will view the evidence most favorably to the non-moving party. *Matsushita Elec. Indus. Co, Ltd. V. Zenith Radio Corp.* 475 U.S. 574, 587-88 (1986). Summary judgment should be granted only in those rare instances where there is no genuine dispute as to material facts.

IV. PLAINTIFF'S CLAIMS ARE NOT BARRED BY THE TWO YEAR STATUTE OF LIMITATIONS SINCE THE DISCOVERY RULE APPLIES

Triable issues of fact exist as to when Ms. Evans should have discovered both the harm caused by Defendant's product and the source of the harm. Utah incorporates the "discovery rule" pursuant to which the two year statute commences to run "from the time the individual who would be the claimant in such action *discovered, or in the exercise of due diligence should have*

discovered, both the harm and its cause." *Bridgewaters v. Toro Co.*, 819 F. Supp. 1002, 1007 (D. Utah 1993)

Contrary to the representations made by Defendant in their moving papers, Ms. Evans testified that she did not appreciate that the mesh could be causing her problems until she read a 2010 Reader's Digest article and that this was "the first written thing" she had ever seen about it (See Ex. A, Evans deposition at p. 95, lines 5 – 14) and that this was "finally" some "documented information that said the mesh could be a problem (See Ex. A, at p. 96, lines 4 – 9). She further testified that even after reading the article, when she went to see Dr. Stout (her surgeon who implanted the mesh) about it before visiting the doctor mentioned in the article (Dr. Raz, who performed her removal), Dr. Stout told her that she ("Dr. Stout") could, at that time, "not say it was the mesh causing the problem" even after performing an exam and ordering X-rays (See Ex. A, at p. 101, lines 11 – 19, p. 102, lines 18 – 25 and p. 103, lines 1 - 16).

Defendant's sole piece of "evidence" they rely upon in asserting the statute bar is a conversation Plaintiff had with a chiropractor Dr. Brouse, in 2009, who purported to advise her that she had high toxicity petroleum levels in her body. However, there is no indication that this was sufficient to trigger the statute of limitations as numerous doctors, including the implanting surgeon, repeatedly failed to tie Plaintiff's symptoms to the mesh and in fact, Ms. Evans testified that she did not discuss with Dr. Brouse whether the petroleum levels "might me related in some way to the mesh" because at the time she spoke with Dr. Brouse in 2009, she did not know the mesh was made with petroleum products. She did not become aware of this possibility until she read the 2010 article and then spoke with the author of the article (see Ex. A, at p. 136, lines 11 – 25 and p. 137, lines 1 - 16).

At a minimum, Ms. Evan's testimony raises a triable issue of fact as to when, under the discovery rule, her causes of action accrued.

V. UNDER UTAH LAW, THE "LEARNED INTERMEDIARY DOCTRINE" DOES NOT PRECLUDE PLAINTIFF'S FAILURE TO WARN CAUSE OF ACTION

Defendant wrongly contends that the "learned intermediary doctrine" bars Plaintiff's failure to warn claim because Defendant had a duty to warn only Dr. Stout and not Plaintiff herself.

- 1) Defendant has produced no evidence that any warning provided to Dr. Stout was adequate and in any event, the issue of adequacy is a factual issue precluding summary judgment.

Doctors become "learned intermediaries" only when they have received adequate warnings from the drug manufacturer. *See Amore v. G.D. Searle & Co.*, 748 F. Supp. 845, 850 (S.D. Fla. 1990). The adequacy of warnings concerning drugs is generally a question of fact (See *Grange v. Mylan Labs, Inc.* 2008 U.S. Dist. LEXIS 92460, 2008 WL 4813311 (2008) at p. 21-22). The following considerations are applied in determining whether a warning is adequate as a matter of law:

"1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it and, ... 5. the means to convey the warning must be adequate." *Pittman v. Upjohn Co.*, 890

S.W.2d 425, 429 (Tenn. 1994) (quoting *Serna v. Roche Labs.*, 101 N.M. 522, 684 P.2d 1187, 1189 (N.M. Ct. App. 1984)).

Here, there is no evidence whatsoever that any warning supposedly provided to Dr. Stout meets the above criteria. And, in fact, the above criteria indicates that whether a warning is adequate to shield a manufacturer from liability under a duty to warn theory is generally a question of fact precluding summary judgment. In applying the learned intermediary doctrine to an inadequate warning claim, a mere reference to an adverse effect is not necessarily an "adequate warning." *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 266-67 (5th Cir. 2002).

One of Ms. Evan's primary complaints is chemical toxicity from the Defendant's Prolene mesh and resulting auto-immune reaction (See Ex. B, Ostergard Rule 26 report, paragraph 23). Defendant has produced no evidence suggesting it adequately warned that patients implanted with the Prolene mesh could suffer such reactions.

2) Dr. Stout did not testify that she did not read information provided by the Defendant.

Defendant cites cases for the proposition that because Dr. Stout did not review information provided by Defendant summary judgment is appropriate. However, this is not what Dr. Stout said at her deposition. Specifically, Dr. Stout testified as follows:

Q: Okay. And do you recall looking at the instructions for use with respect to the Ethicon product at all?

A: I don't recall.

Q: Would that have been a source that you would have looked at for information on any kind of adverse events?

A: Probably not.

(See Ex. C, Stout deposition at p. 45, lines 1 – 8)

This testimony does not establish, for summary judgment purposes, that Dr. Stout did not read the materials but only that, as she sat at her deposition, she did not recall if she had. Nor does her testimony establish for summary judgment purposes that she did not rely upon the materials, only that she “probably” wouldn’t have.

3) The Defendant has produced no evidence to support its position that an alternative warning would not have altered Dr. Stout’s use of the product.

A defendant can offer testimony that a different warning would not have made a difference in the actions of the physician. If a manufacturer rebuts a presumption of causation, then the plaintiff must establish proximate cause by showing that, had the manufacturer issued a proper warning to the physician, the physician would have altered her behavior and injury would have been avoided. See *Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095, 1127 (D. Kan. 2002). To create a factual question, the evidence must be of sufficient weight to establish at least some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug. See *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992); *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 660 (1st. Cir. 1981).

Here, Defendant has offered no evidence whatsoever to support its claim that a different warning would not have altered Dr. Stout’s use of the product. Defendant merely cites Dr.

Stout's testimony that she couldn't recall reviewing the documentation and it "probably" wouldn't have mattered. Defendant could have asked Dr. Stout if an alternative warning would have altered her behavior but Defendant chose not to do so. As such, Defendant has not met its evidentiary burden to prevail on its summary judgment motion.

4) Defendant may be held strictly liable.

Under Utah law, a manufacturer may also "be held strictly liable for any physical harm caused by its failure to provide adequate warnings regarding the use of its product." *House v. Armour of Am., Inc.*, 929 P.2d 340, 343 (Utah 1996). "Where a manufacturer knows or should know of a risk associated with its product, the absence or inadequacy of warnings renders that product unreasonably dangerous, subjecting the manufacturer to strict liability." *Id.* (quotation omitted). Moreover, "[a] manufacturer . . . may have a duty to warn of latent dangers even if there is no feasible way to produce a safer product; the purpose of the warning is to enable the user to take appropriate steps to avoid the hazard." *Wankier v. Crown Equipment Corp.*, 353 F.3d 862, 867 (10th Cir. 2003).

VI. PLAINTIFF'S DESIGN DEFECT CLAIMS ARE NOT SUBJECT TO SUMMARY JUDGMENT BECAUSE THERE ARE TRIABLE ISSUES OF FACT AS TO WHETHER THE PRODUCT CONTAINS A MANUFACTURING DESIGN DEFECT

A consulting firm retained by Defendant to examine possible causes of mesh erosion determined that the manufacturing process for Ethicon's mesh products (weaving filaments into mesh, heat sealing, etc....) causes deformation of the surface of the filaments and debris on the filament surface. (Exhibit D , PA Consulting Report, pp. 24 – 33). Furthermore, the consultant's report notes that the mesh construction process is known to alter the surface characteristics of the

filaments. *Id.* at 37. This report raises a triable issue of fact as to whether Defendant's mesh contains a manufacturing design defect.

VII. SUMMARY JUDGMENT IS NOT APPROPRIATE ON PLAINTIFF'S FRAUD BASED CLAIMS

Defendant wrongly asserts that Plaintiff's claims for Fraud, Fraudulent Concealment, Negligent Misrepresentation and Constructive Fraud should be dismissed. The requirements to state a common law fraud claim in Utah are as follows:

- (1) That a representation was made (2) concerning a presently existing material fact; (3) which was false; (4) which the representor either (a) knew to be false, or (b) made recklessly, knowing that he [or she] had insufficient knowledge upon which to base such representation; (5) for the purpose of inducing the other party to act upon it; (6) that the other party, acting reasonably and in ignorance of its falsity; (7) did in fact rely upon it; (8) and was thereby induced to act; (9) to his [or her] injury and damage. See *Crookston v. Fire Ins. Exch.*, 817 P.2d 789, 800 (Utah 1991) (quoting *Pace v. Parrish*, 122 Utah 141, 247 P.2d 273, 274-75 (Utah 1952)).

Or, of course, in the case of concealment, concealing a material fact in an effort to induce certain action or non-action to the detriment of the innocent party.

In seeking summary judgment, Defendant does not address any of the above elements but instead seeks to assert the fraud claims are merely duplicative of the failure to warn claims and disposed of due to Defendant's misapplication of the "learned intermediary doctrine.". As discussed, Defendant's learned intermediary arguments fail as to Plaintiff's failure to warn claims. Furthermore, Defendant cites no Utah authority to support its position that Plaintiff's fraud claims are impacted by the learned intermediary doctrine. Further, contrary to Defendant's

assertions, Ms. Evan's fraud based claims do not rely on communications between Defendant and Dr. Stout. Instead, Plaintiff will rely on communications directly from Defendant, such as Defendant's brochures and literature, and on Defendant's non-disclosure of material information in seeking recovery on her fraud-based theories.

VIII. CONCLUSION

For all of the foregoing reasons, Plaintiff respectfully submits that summary judgment be denied on all of Plaintiff's claims except for Plaintiff's unjust enrichment claim which is withdrawn.

Dated: April 22, 2016

Respectfully submitted,

/s/ Mark A. Milstein

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 22, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/Mark A. Milstein
Attorney for Plaintiff